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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,509	10/05/2005	Noritada Katayama	2005_1546A	2516

513 7590 03/18/2009

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EXAMINER	
NAQI, SHARICK	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,509	KATAYAMA, NORITADA	
	Examiner	Art Unit	
	SHARICK NAQI	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-13,17-19 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-13,17-19 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant Regarding Claim Interpretation

The word "for" and the phases "configured to" and "adapted to" in the claim(s) may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Examiner has placed the word "for" and the phases "configured to" and "adapted to" in italics, see below, for those instances where this interpretation applies.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "third biological information sensor modules" added to claim 6, line 3, claim 24, line 2 and claim 25, line 2 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not

be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 6, line 3, claim 24, line 2 and claim 25, line 2, the applicant has claimed "third biological information sensor modules for issuing a warning when said measurement calculating unit detects an abnormality." The Examiner is unable

to find any prior mention of the "third biological information sensor modules" in the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-13, 17-19 and 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In independent claims 21, 22 and 23, line 9, the applicant claims a "measurement calculating unit However, it is unclear if the measurement calculating unit is structure, or an algorithm or software. In the specification on page 10, lines 6-7, applicant states that “on the main board 4 put on the sensor board 5, there are mounted a main integrated circuit 20 *including* a measurement calculating unit”. This disclosure does not clarify whether the measurement calculating unit is structure ,or an algorithm or software because either one of these could be “included” on a main integrated circuit. If the determination means is an algorithm or software then the term/limitation will not be given patentable weight because it lacks structure that would be attributed to the apparatus claims.

Additionally, claims dependent on independent claims 21, 22 and 23 are rejected as being dependent on a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8, 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamb USPN 3,651,694 in view of Alvarez USPN 6,238,354 and Journal of Nursing Science, December 31, 1990 (Hereinafter JNS, provided in IDS)

In regards to claim 21, Lamb discloses a biological information monitoring system comprising

a plurality of biological information sensor modules *adapted to* be attached to the right side and left side of a subject body, said biological information sensor modules each incorporating a biological information sensor *for* detecting biological information and wherein said plurality of biological information sensor modules includes at least a first biological information sensor module and a second biological information sensor module, wherein said first biological information sensor module includes a measurement calculating unit *configured to* determine an abnormality by comparing said biological information detected by said biological information sensor in the first biological information sensor module itself with biological information sent from said second biological information sensor module, wherein said biological information detected by said biological

information sensor is at least one of body temperature, pulse and blood pressure, (*Lamb column 1, lines 30-75*).

Lamb does not disclose that the biological sensor modules each incorporate a communicator *for* communicating said biological information by wireless. Lamb also does not disclose that at least one of said biological information sensor modules includes the determination means for performing determination of abnormality by comparing said biological information detected by said biological information sensor in the biological information sensor module itself with biological information sent from the other biological information sensor module through said communicator. However Alvarez, a reference in an analogous art, discloses a temperature monitoring assembly for continuously monitoring a patient from a remote location with two biological information sensor modules on a user's left and right arms wherein the determination means for calculating the temperature is on one sensor module. The determination means averages biological information detected by said biological information sensor in the biological information sensor module itself with biological information sent from the other biological information sensor module using wireless communication (*Alvarez Fig. 4, column 2, lines 1-45, column 7, lines 5-34*). It would have been obvious to one having ordinary skill in the art to substitute the wired sensor modules of Lamb with Alvarez's wireless temperature monitoring assembly because Alvarez teaches that the wireless device allows for continuous remote monitoring of body temperature of a patient such as a small child during the night or while sleeping and this is important because if onset of increased

temperatures are allowed to go unobserved they can result in permanent damage to a patient (*Alvarez column 2, lines 5-10 and lines 35-40*).

Lamb modified by Alvarez discloses actuating an alarm when a temperature difference the temperature difference greater than 5 degrees (*Lamb column 3, lines 24-35*)

Lamb modified by Alvarez does not disclose wherein a temperature difference not lower than 0.5 °C between the body temperatures measured on the right and left sides of the subject is determined as abnormal by said measurement calculating unit. However JNS, a reference in an analogous art, discloses that when the temperature difference between the left and right side of a patient was greater than 0.6 degrees C (this meets the limitation not lower than 0.5 degrees C) 9 patients out of 14 died and the remainder had serious problems (*JNS page 2, discussion point 1*). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Lamb and Alvarez by switching the temperature different that sets off an alarm from greater than 5 degrees to greater than 0.6 degrees as taught by JNS, because JNS teaches that when the temperature difference between the left and right side of a patient was greater than 0.6 degrees C 9 patients out of 14 died and the remainder had serious problems (*JNS page 2, discussion point 1*).

6. The biological information monitoring system set forth in claim 21, wherein said plurality of biological information sensor modules further comprises third biological information sensor modules *for* issuing a warning when said

measurement calculating unit detects an abnormality (*Alvarez Figure 5, column 6, lines 30-58, alarm*).

7. The biological information monitoring system set forth in claim 21, wherein said communicator is *configured fo*r communicating with the outside to release a determination result of said measurement calculating unit by wireless, and wherein said system comprises an external electronic device for receiving said determination result outputted from said measurement calculating unit (*Alvarez Figure 5, column 4, lines 65-67, column 5, lines 1-15*).

8. The biological information monitoring system set forth in claim 21, wherein at least one of said biological information sensor modules incorporates a memory *for* storing at least one of a determination result outputted from said measurement calculating unit and the biological information measured by said biological information sensor (Alvarez *Column 5, lines 60-67, reset button has to erase the data, therefore the data must be stored in memory in order to be erased*).

Claim 11 is rejected on the same basis as claim 21.

Claims 10, 13, 23, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. US Patent Number 5,724,980 (hereinafter Nakamura) in view of Inagaki et al. US Patent Number 6,344,025

(hereinafter Inagaki) and *Journal of Brain and Nervous Diseases*, December 31, 1996 (Hereinafter JBND, provided in IDS).

In regards to claim 23, Nakamura discloses a biological information monitoring system comprising

a plurality of biological information sensor modules *adapted to* be attached to the right side and left side of a subject body (*Nakamura Fig 1, column 2, lines 44-67 and column 3, lines 1-9.Sensor portion 11a is one sensor module and sensor portion 11b along with processor 2 is a second sensor module)*,

said biological information sensor modules each incorporating a biological information sensor *for* detecting biological information (*Nakamura Fig 1, column 2, lines 44-67 and column 3, lines 1-9. The sensors detect blood pressure)*,

wherein said plurality of biological information sensor modules includes at least a first biological information sensor module and a second biological information sensor module (*Nakamura Fig 1, column 2, lines 44-67 and column 3, lines 1-9.Sensor portion 11a is one sensor module and sensor portion 11b along with processor 2 is a second sensor module)*,

wherein said first biological information sensor -module includes a measurement calculating unit *configured to* determine an abnormality by comparing said biological information detected by said biological information sensor in the first biological information sensor module itself with biological information sent from said second biological information sensor module (*Nakamura Fig 1, column 2, lines 44-67 and column 3, lines 1-9. Sensor portion 11b connected with processor 2 comprises the sensor module with*

determination means because the processor determines whether the difference between the two blood pressures measurements is over a predetermined value),

wherein said biological information detected by said biological information sensor is at least one of body temperature, pulse and blood pressure (*Nakamura Fig 1, column 2, lines 44-67 and column 3, lines 1-9. The sensors detect blood pressure)*,

Nakamura further discloses that the two sensors/blood pressure cuffs send information via a wired connection (*Nakamura Fig. 1*).

Nakamura does not disclose that the sensors/blood pressure cuffs include a communicator configured to communicate said biological information by wireless and that the information is sent from one biological information sensor module to another through said communicator. However Inagaki, a reference in an analogous art discloses a blood pressure monitor where a cuff is provided with transmission and reception portions (equivalent to a communicator) to communicate measured signals wherein the communications are wired or wireless (*Inagaki column 1, lines 60-67 and column 4, lines 35-45*). Both references disclose blood pressure cuffs for determining a user's blood pressure. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nakamura's blood pressure measuring cuffs that communicate via a wired connection with Inagaki's cuff including transmission and reception portions (equivalent to a communicator) for communicating measured signals wirelessly because Inagaki teaches that a wireless connection

improves operability of the blood pressure monitoring device (*Inagaki column 2, lines 18-22*).

Nakamura modified in view of Inagaki would have a processor that compares data from both right and left cuffs to determine whether the difference between the two blood pressures measurements is over a predetermined value and display a warning in that case (*Nakamura column 3, lines 1-19*). Nakamura and Inagaki do not disclose a particular number for the predetermined value and therefore do not disclose the limitation wherein a blood pressure difference not less than 10 mmHg between the blood pressures measured on the right and left sides of the subject is determined as abnormal by said measurement calculating unit. However JBND, a reference in an analogous art, discloses that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg (this meets "not less than 10 mmHg" because it is greater) is of important clinical significance (*JBND page 3, lines 1-4*). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Nakamura and Inagaki to set the predetermined difference value to cause a warning at greater than 15mmHg as taught by JBND, because JBND teaches that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg is of important clinical significance (*JBND page 3, lines 1-4*).

10. The biological information monitoring system set forth in claim 23, wherein at least one of said biological information sensor modules incorporates a

memory *for* storing at least one of the determination result outputted from said measurement calculating unit and the biological information measured by said biological information sensor (*Nakamura Figure 1, processor 2 and display 3 that makes determination and displays the result would inherently have memory*).

13. The biological information monitoring system set forth in claim 23, wherein said system further comprises an electronic device *for* transmitting data to said biological information sensor module by wireless, and. wherein said measurement calculating unit performs abnormality determination with reference to said data sent from said electronic device (*Nakamura as modified by Inagaki for the rejection of claim 23 above would have two blood pressure cuffs communicating wirelessly where the processor compares data from both to determine whether the difference between the two blood pressures measurements is over a predetermined value. The cuff without the processor would meet the limitation of an electronic device for transmitting data to said biological information sensor module by wireless, so as to perform abnormality determination with reference to said data sent from said electronic device in said determination means*).

25. The biological information monitoring system set forth in claim 23, wherein said plurality of biological information sensor modules further comprises third biological information sensor modules *for* issuing a warning when said

measurement calculating unit detects an abnormality (*Nakamura Column 3, lines 10-18. Warning*).

27. The biological information monitoring system set forth in claim 23, wherein at least one of said biological information sensor modules incorporates a communicator *for* communicating with the outside to release a determination result of said measurement calculating unit by wireless, and wherein said system comprises an external electronic device *for* receiving said determination result outputted from said measurement calculating unit (*Inagaki figure 3*).

Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lamb, Alvarez and JNS as applied to claim 21 above, and further in view of JBND.

Lamb, Alvarez and JNS teach monitoring temperature differences between left and right sides of a patient. Lamb, Alvarez and JNS also teach that typical monitoring devices in hospitals are designed to concurrently monitor plurality of patient functions including temperature and blood pressure (Alvarez column 1, lines 21-25).

Lamb, Alvarez and JNS do not disclose the biological information monitoring system set forth in claim 21, wherein each of said biological information sensors detects at least the blood pressure, and wherein a blood pressure difference not less than 10 mmHg between the blood pressures measured on the right and left sides of the subject is determined as abnormal by

said measurement calculating unit. However JBND, a reference in an analogous art, discloses that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg (this meets "not less than 10 mmHg" because it is greater) is of important clinical significance (*JBND page 3, lines 1-4*). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Lamb, Alvarez and JNS to also monitor blood pressure and set a warning when the difference between left and right side blood pressure greater than 15mmHg as taught by JBND, because Lamb, Alvarez and JNS teach that typical monitoring devices in hospitals are designed to concurrently monitor plurality of patient functions including temperature and blood pressure (*Alvarez column 1, lines 21-25*) and JBND teaches that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg is of important clinical significance (*JBND page 3, lines 1-4*).

Claims 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lamb, Alvarez and JNS as applied to claim 7 above, and further in view of Besson et al. USPN 5,862,803 (hereinafter Bessen).

In regards to claim 17, Lamb, Alvarez and JNS do not disclose that the biological information monitoring system set forth in claim 7, wherein said communicator transmits identification signals *for* distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to

figure out said identification signals and said determination result, to thereby identify the individual living subjects.

However Besson et al., a reference in an analogous art, discloses a wireless medical diagnosis system with biological sensor modules (*Bessen Abstract and column 13, lines 25-45*). Each module is assigned an identification code corresponding to the patient to whom it is attached. An external device can then differentiate between data received from different patients' sensor modules by using the identification code received with the data (*Bessen Column 8, lines 5-25*). This is equivalent to the claim limitation of wherein said communicator transmits identification signals *for* distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to figure out said identification signals and determination result, to thereby identify the individual living subjects. It would have been obvious to one of ordinary skill in the art at the time of invention to improve the invention of Lamb, Alvarez and JNS by using Besson's technique of having identification codes for each sensor module corresponding to the patient to whom the sensor module is attached such that the external device receiving data can use the received identification code to differentiate between data from different patients and their sensor modules because it would provide the benefit of preventing confusion between different patients' data and make the device capable of simultaneously serving several patients in a room (*Bessen Column 8, lines 5-25*).

Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura, Inagaki and JBDS as applied to claim 27 above, and further in view of Besson et al. USPN 5,862,803 (hereinafter Bessen).

In regards to claim 19, Nakamura, Inagaki and JBDS do not disclose the biological information monitoring system set forth in claim 27, wherein said communicator transmits identification signals *for* distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to figure out said identification signals and determination result, to thereby identify the individual living subjects.

However Besson et al., a reference in an analogous art, discloses a wireless medical diagnosis system with biological sensor modules (*Bessen Abstract and column 13, lines 25-45*). Each module is assigned an identification code corresponding to the patient to whom it is attached. An external device can then differentiate between data received from different patients' sensor modules by using the identification code received with the data (*Bessen Column 8, lines 5-25*). This is equivalent to the claim limitation of wherein said communicator transmits identification signals *for* distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to figure out said identification signals and determination result, to thereby identify the individual living subjects. It would have been obvious to one of ordinary skill in the art at the time of invention to improve the invention of Nakamura, Inagaki and JBDS by

using Besson's technique of having identification codes for each sensor module corresponding to the patient to whom the sensor module is attached such that the external device receiving data can use the received identification code to differentiate between data from different patients and their sensor modules because it would provide the benefit of preventing confusion between different patients' data and make the device capable of simultaneously serving several patients in a room (*Bessen Column 8, lines 5-25*).

Response to Arguments

Applicant's arguments with respect to claims 4-13, 17-19 and 21-27 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments against the 35 USC 112 Second Paragraph rejection are addressed by the amended rejection above.

Applicant is invited to request an interview to discuss suggestions to overcome the applied prior art.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on September 24, 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARICK NAQI whose telephone number is (571)272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. N./
Examiner, Art Unit 3769

/Michael C. Astorino/
Primary Examiner, Art Unit 3769

March 15, 2009